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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,121	11/27/2000	Gautam Khurana	07039-296001	5932

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EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/723,121

Applicant(s)

KHURANA ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12,14-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-9,15-20 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,5,10-12,14,21-27,29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

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DETAILED ACTION

Claims 1, 3-12, 14-27 and 29 are pending in the application.

This Office Action is in response to the Amendment filed on 7/10/02.

Response to Amendment

The objection to claim 28 has been withdrawn in light of Applicants cancellation of the claim.

The rejection of claims 6-9, 19, 20, 21-29 under 35 U.S.C. 112, second paragraph has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 1, 4-6, 10, 11, 14, 17, 19 and 20 under 35 U.S.C. 102 (b) has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 12, 17, 19 and 20 under 35 U.S.C. 103 (a) has been withdrawn in light of Applicants' amendment of the claims.

Claims 21-27 and 29 are rejected under 35 U.S.C. 112, second paragraph for reasons discussed below.

Claims 1, 3, 4, 5, 10 and 21 are rejected under 35 U.S.C. 102 (e) for reasons discussed below.

Claims 11, 12 and 14 are rejected under 35 U.S.C. 103 (a) for reasons discussed below.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 21-27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 21-27 and 29 recites "a device for delivering ... comprising a housing... and a contact surface..." However, it is unclear whether the housing and contact surface are separated or connected. Applicants need to amend the claims to provide a clearer picture of said device.

Claim Rejections - 35 USC § 102

Claims 1, 3, 4, 5, 10 and 21 are drawn to a method of delivering a pharmaceutical composition comprising DNA, RNA, antisense and ribozyme...etc to a tissue site by providing a gene delivery device with a contacting surface, applying said pharmaceutical composition to said contact surface, and contacting said contact surface to said tissue site, wherein said contacting is by moving said contact surface back and forth or a circular motion. The claims are further drawn to delivering nucleic acid to tissues such as wound or intact skin by using said method. The claims are further drawn to a device for delivery pharmaceutical composition that comprises a housing, a contact surface that comprises bristles.

Claims 1, 3, 5 and 10 rejected under 35 U.S.C. 102(e) as being anticipated by MacCall et al (6,004,806).

MacCall et al disclose therapeutic compositions comprising a ribozyme directed against bacterial infection formulated into a cream. MacCall et al. disclose that said cream can be applied to the site of infection (col.12, lines 18-28). Applying cream to the site of the infection (either wounded or intact skin/mucosa) comprises applying the cream to a finger (a contact surface) and subsequently contacts the finger with cream to the tissue site, wherein such contacting can be moving the finger back and forth or in circular motion at the tissue site. Therefore, MacCall et al. disclose the instantly claimed invention.

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Claims 1, 3, 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Vicente et al. (1987, abstract)

Vicente et al. teach a method of inoculating virus to plant by brushing the leaves. Such method also delivers DNA or RNA to a tissue site by a device with a contact surface that is bristle (see line 2 of abstract). Therefore, Vicente et al. disclose the instant claimed invention.

Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Serra et al (5,681,335).

Serra et al. disclose a mini brush that has soft, flexible bristles with a lumen for delivering pharmaceutical compositions to dissolve a fibrinous obstruction (see Figure 1, and abstract). Therefore, Serra et al. disclose the instantly claimed invention.

Claim Rejections - 35 USC § 103

Claims 11, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vicente et al.

The claims are drawn to a kit comprising a gene delivering device comprising a contact surface with bristles and a pharmaceutical composition comprising a nucleic acid. The claims are further drawn to said kit further comprising a dye and a nucleic acid, wherein the nucleic acid is DNA, RNA, antisense molecule, etc.

The teaching of Vicente et al. is discussed above. However, Vicente et al. do teach a kit with the brush and a pharmaceutical composition comprising a nucleic acid and a dye.

It would have been obvious to one of ordinary skill in the art to make a kit with the nucleic acid, a dye and a delivery device as taught by Vincent et al. Vincent et al. teach that

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brush can be used to deliver viral DNA to plant tissues. The ordinary artisan would have been motivated to include the nucleic acid in such a kit to make it easy for the inoculation process.

The ordinary artisan would have been motivated to include a dye to monitor the site of monitor whether the composition has reached the desired tissue site. The ordinary artisan would have a reasonable expectation of success because making a kit with the brush and viral DNA stock and mixing a dye in the pharmaceutical composition is a routine practice. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claims 22-27 are objected to for being dependent on a rejected claim.


Claims 6-9 and 15-20 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
October 21, 2002


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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